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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,653

11/20/2006

David B. Weiner

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EXAMINER

LI, BAO Q

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,653	<b>Applicant(s)</b> WEINER ET AL.	
	<b>Examiner</b> BAO LI	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10-15 and 17-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The amendment and response filed on March 23, 2009 have been acknowledged. Claims 1, 4, 7, 10, 13-15, 17 have been amended. Claims 3, 9, 16 have been canceled. New claims 25-26 have been added.

In summery, claims 1-2, 4-8, 10-15 and 17-26 are pending and considered within the elected scope of Ox40.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. (Withdrawn) The rejection of claims 1-2 , 7, 15, 22-24 under 35 U.S.C. 102(a) as being anticipated by Taylor et al. (J. Leukocyte Biology Sept. 2002, Vol. 72, pp. 522-529) has been withdrawn necessitated by Applicants' amendment.

3. (Withdrawn) The rejection of claims 1, 2, 7, 8, 13, 15, 22, 23 and 24 under 35 U.S.C. 102(b) as being anticipated by Zhan et al. (DNA AND CELL BIOLOGY, 2000, Vol. 19, No. 11, pp. 637-645) has been removed necessitated by Applicants' amendment.

4. (Maintained) Claims 1-2, 4-5, 13, 22 are still under 35 U.S.C. 102 (b) as being anticipated by US Patent No. 6,017,735A to O'Hare et al.

5. Applicants traverse the rejection and submit that the coupled/fusion proteins taught by O'Hare et al. is the fusion protein comprising herpes virus VP22 and any other protein including

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Ox40 , wherein the nucleic acid sequence is constructed as a fusion protein encoding the fusion protein, rather than a separated nucleic acid molecules. Moreover, all coupled or fusion proteins are necessarily coupled with VP22, because the VP22 are provided in order to help for directing /translocating the proteins.

6. Applicants' argument has been respectfully considered. However, it is not found persuasive for withdrawn the rejections for claim 1 and its dependent claims, since the disclosure by O'Hare et al. still encompass the rejected claims 1-2, 4-5, 13, 22 and 25.

7. Because a reasonable interpretation of the broadest scope of claims 1-2, 4-5, 13, 22 is explained as two nucleic acid sequences encoding VP22 and other protein that is not limited to connected each other directly, they can be a nucleic acid coding sequence encoding VP22 and other protein, including the immunoregulatory protein OX40 are located in the same nucleic acid sequence but can be separated with a linker in between the two molecules. Applicants also interpreted the separate nucleic acid molecules cited in claims 1, 7 and 8 like this. For example, Applicants in the response states that claim 1 is amended to refer to the nucleic acid coding sequence encoding the immunomodulatory protein being on a separate nucleic acid molecule as the nucleic acid coding sequence encoding the immunogen.

8. Therefore, the fusion protein encoded by a polynucleotide sequence encoding VP22 and OX40 directly connected each other is only one embodiment of the O'Hare's disclosures. O'Hare also teach that their coupled proteins/fusing protein is also constructed as a nucleic acid sequences encoding a proteins with the herpesvirus protein VP22 situated in the sequence indirectly or separately with a linker sequence in between, wherein the linker located in between the coupled/fusion protein with the VP22 enables the fusion protein and VOP22 to be split intercellularly and separately into two parts as the antigenic or a biological protein/polypeptide and the transporter protein VP22 (lines 17-25 in column 14). Therefore, the disclosure of O'Hare still meets the limitation of claim 1 ad amended. The rejection for these claims is maintained.

9. (Maintained) Claims 7-8, 10, 15, 17-19, 25-26 are still rejected under 35 U.S.C. 102 (e) as being anticipated by Emtage et al. (US2003/0113919A1).

10. For this rejection, Applicants asserted that the reference by Emtage et al. [0066 paragraph] only teaches using the polynucleotide encoding the polypeptide of OX40L (OX40 ligand) rather than OX40 (receptor). Therefore, it cannot anticipate claims as amended.

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11. Applicants' argument has been respectfully considered; however, it is not persuasive to withdraw the rejection on claims 7-8, 10, 15, 17-19, 25-26, since OX40L is still cited in these claims. The disclosure still meets the limitation of these claims. The rejection is maintained.

12.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. (Maintained). Claims 7-8, 10-12, 15, 17-19, 25-26 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Emtage et al. (US2003/0113919A1) in view of Clement et al. (J. Infect. Dis. 2002, 185, pp. 165-173).

15. In the response, Applicants asserted that the reference by Emtage et al. [0066 paragraph] only teaches using the polynucleotide encoding OX40L (OX40 ligand) rather than OX40 (receptor). Therefore, it cannot anticipate claims as amended.

16. Applicants' argument has been respectfully considered; however, it is not persuasive to withdraw the rejection on claims 7-10, 15, 17-19, 25-26, since OX40L is still cited in these claims.

17. (Withdrawn) The rejection of claims 1-19 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,017,735A to O'Hare et al. in view of Clement et al. (J. Infect. Dis. 2002, 185, pp. 165-173) has been withdrawn necessitate by Applicants' amendment and the argument. Especially, Applicants point out that the herpes virus VP22 is the essential protein for the coupled protein that teaches away from replacing VP22 with a different protein, such as HSV2gD.

**(1) New grounds of rejections:**

18. Upon further considering the claims and applications, further rejections are made on the record:

***Priority***

1. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 112, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be

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included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

***Informality issues***

Please spell out the complete names for all short abbreviations cited in specification and claims 1, 7 and 15.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-2, 4-8, 10-15, 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1, 7, 15, 22, 23 are vague and indefinite in that the metes and bounds of the cited "functional fragment thereof" are not defined. The claims are interpreted in light of the specification; however, the specification does not have the definition for this. Therefore, the metes and bounds of this term cannot be determined.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2, 4-8, 10-15 and 17-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. Applicants do not have a possession for having any functional fragment of OX40 and composition comprising it as well as a method using the same.

7. To determine whether Applicants have a possession for the claimed subject or the claimed subject matter lacks of a written description, it is considered based on 1). Full coverage of the claimed scope of invention; 2). Whether applicant provides sufficient support to support the full scope of the invention and 3). Whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing according to the disclosure of the entire application. This should include the following aspects of the considerations:

- a. Actual reduction to practice;
- b. Disclosure of drawings or structural chemical formulas;
- c. Sufficient relevant identifying characteristics including for following aspects:
  - i). Complete structure,
  - ii). Partial structure;
  - iii). Physical and/or chemical properties and
  - iv). Functional characteristics when coupled with a known or disclosed correlation between function and structure;
- d. Method of making the claimed invention;
- e. Level of skill and knowledge in the art;
- f. Predictability in the art.

8. In the instant case, the pending claims are drawn to a functional fragment of OX40, a composition comprising it and a method for using the same. However, specification does not describe any fragment of OX40, and any method for making and using a fragment of OX40 as a functional fragment. It also lacks of evidence of reduction to the practice. One skilled in the art would recognize that the applicant was in possession of the claimed invention; especially the claimed invention belongs to a very unpredictable filed. For example, it is well known in the art that one amino acid change could change the biological function of a peptide as evidenced by

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Song et al. they describe that a single amino acid change in a biological active protein "survivin" converts it from anti-apoptotic protein to a pro-apoptotic protein (.Mol Biol Cell. 2004 March; 15(3): 1287–1296). The specification does not teach other species of a functional fragment of OX40.

9. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of claimed fragment, the skilled artisan could not immediately recognize or distinguish members of the claimed fragment of OX40. The full breadth of the claims does not meet the written description and enablement provision of 35 U.S.C. 112, first paragraph.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nickol Gary can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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